

Docket No.: 4518-0107PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hans LOIBNER et al.

Application No.: 10/519,323

Confirmation No.: 9319

Filed: December 23, 2004

Art Unit: 1643

For: PREPARATION BASED ON AN ANTIBODY
DIRECTED AGAINST A TUMOR-
ASSOCIATED GLYCOSYLATION SUCH AS
LEWIS STRUCTURES

Examiner: NATARAJAN, Meera

STATEMENT OF THE INTERVIEW

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants thank the Examiners for graciously agreeing to the interview. Applicants provide their statement of the interview and remarks below.

Remarks begin on page 2 of this paper.

Applicant's Summary of Examiner Interview, Tuesday April 22, 2008, 12:00.

Claims Discussed

Applicants presented claims 2, 35, 36, and 48 for substantive discussion.

Specific Prior Art Discussed

Applicants discussed prior art references Saleh and Basu. The new limitation of said antibody not inhibiting binding of its ligand (EGF) overcomes the prior art reference Saleh et al. Thus Applicants submit that the amendments filed February 25, 2008 overcome the prior art rejection and request the Examiner allow the pending claims.

Other Pertinent Matters Discussed

Claim 35

The Examiners asked whether the antibodies disclosed in the application are publicly available. In reply, Applicants herein provide information regarding the availability of antibodies ABL364 and IGN311. Applicants point out that the specification discloses that ABL364 was obtained from Novartis. Specification page 12, line 35. The specification discloses that IGN311 was produced for the assignee, Igeneon, under GMP conditions by BioInvent. *Id.* Applicants indicate that IGN311 has been widely described in the literature (Google reference provided) and is currently in clinical trials.

Applicants request that, in light of the pending claims and the present discussion, the Examiner withdraw all rejections.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: MAY 12 2008

Respectfully submitted,

By 

Leonard R. Svensson

Registration No.: 30,330

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Attorney for Applicant

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1: [Schuster M, Jost W, Mudde GC, Wiederkum S, Schwager C, Janzek E, Altmann F, Stadlmann J, Stemmer C, Gorr G.](#) [Related Articles, Links](#)

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 Analysis of lysine clipping of a humanized Lewis-Y specific IgG antibody and its relation to Fc-mediated effector function.


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3: [Nechansky A, Schuster M, Jost W, Siegl P, Wiederkum S, Gorr G, Kirchels R.](#) [Related Articles, Links](#)

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 Inhibition of xenograft tumor growth and down-regulation of ErbB receptors by an antibody directed against Lewis Y antigen.


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 Improved effector functions of a therapeutic monoclonal Lewis Y-specific antibody by glycoform engineering.

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 Antibodies directed against Lewis-Y antigen inhibit signaling of Lewis-Y modified ErbB receptors.

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... Introduction: **IGN311** is a fully humanized monoclonal antibody targeting tumors with over-expression of Lewis Y. 60–90% of human carcinomas of epithelial ...

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Inhibition of signaling via erbB-receptors by antibodies that target the Lewis Y-antigen - Alle 7 Versionen »

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P Hinterleitner, P Ganglberger, B Obermüller, B ... - Springer

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Enhanced Tumor Inhibition of MDA-MB-231 Breast Carcinoma by the Anti-Tissue Factor Antibody, CNTO ...

C Ngo, B Scallon, R Tawadros, F McCabe, H Millar, ... - Journal of Immunotherapy, 2004 - [immunotherapy-journal.com](#)

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X Wu, J Hopp, D Perret, J Chung, ME Reif, SM ... - Journal of Immunotherapy, 2004 - [immunotherapy-journal.com](#)

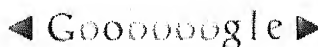
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... Results from a phase I clinical trial with IGN311, a fully humanized IgG1 antibody against Lewis Y in patients with solid tumors expressing Lewis Y antigen. ...

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... The aim of the present study was to produce glycosylation variants of the therapeutic Lewis Y-specific humanized IgG 1 antibody IGN311 to enhance cell-killing ...

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Inhibition of Xenograft Tumor Growth and Down-Regulation of ErbB Receptors by an Antibody Directed ... - Alle 4 Versionen »

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... II, Open Label Trial With the Lewis Y Specific Humanized Monoclonal Antibody IGN311 in Patients With

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